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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,244	09/17/2001	David S. Goldsteen	293/002DIV2	1651
1473	7590	10/09/2003	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			THALER, MICHAEL H	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 10/09/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

NY

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/955,244	GOLDSTEEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 13 August 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) 2-11 and 15-17 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,12-14 and 18-27 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

<p>1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.</p>	<p>4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____.</p> <p>5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6)<input type="checkbox"/> Other: _____.</p>
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Art Unit: 3731

Claims 2-11 and 15-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5. Contrary to applicant's remarks, claims 15-17 do not read on the elected species of figures 5 and 7a-8a. Claim 15 does not read on the elected species of figures 5 and 7a-8a since the distal portion of longitudinal structure (e.g. 210) is not resiliently biased to deflect laterally. Rather, in the elected species of figures 5 and 7a-8a, guide structure 250 is biased to deflect laterally. Claim 16 does not read on the elected species of figures 5 and 7a-8a since, in the embodiment figures 5 and 7a-8a, it is the elongated guide structure 250 rather than any portion of the longitudinal structure that makes an initial penetration of the side wall.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The claimed terms "elongated guide structure" and "longitudinal structure" must be defined in the specification.

Claims 12, 13 and 18-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 3731

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This application is a continuation of Serial No. 09/323,181 which is a continuation of Serial No. 08/745,618. There is no basis in the original disclosure of Serial No. 08/745,618 for the following limitations: the text from "to" in line 5 to "point" in line 7 of claim 12; "sharpened" in claim 13, line 3, (Longitudinal structure 220 is described as being tapered on page 17, line 11. However, a tapered structure is not necessarily sharpened.); the distal portion of the longitudinal structure being defined as a member rather than a portion in e.g. claim 18, lines 2-4 (There is no description in the drawings or specification that only the distal portion of longitudinal structure 210 comprises a separate tubular member). Claims 21 and 24 have the same problem.

Claims 12, 13 and 18-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of these claims is unclear for the reasons set forth in the paragraph above. In claim 24, line 16, there is no antecedent basis for "said apertures" (plural).

Art Unit: 3731

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 12 and 13, 18-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taylor (3,952,742). Taylor discloses elongated guide structure 14 and longitudinal structure 12, a distal portion 12c of the longitudinal structure 12 adapted to penetrate tissue (when guide structure 14 is inserted therein). The elongated guide structure 14 is inherently capable of being insertable into a tubular organ (e.g. an intestine) and extendable along the interior of tubular organ to a point where an aperture may be created

Art Unit: 3731

through the side wall of the tubular organ which is remote (to some extent) from the location at which the instrument is inserted into the tubular member since elongated guide structure 14 may be 8 inches long (col. 2, lines 37-38). The longitudinal structure 12 is inherently capable of penetrating the side wall (when guide structure 14 is inserted therein) since longitudinal structure 12 and guide structure 14 together are inherently capable of being pushed outwardly through the side wall where the tubular member curves to the side while the instrument 12, 14 remains straight. Alternatively, it would have been obvious that the elongated guide structure 14 is capable of being insertable into a tubular organ (e.g. an intestine) and extendable along the interior of tubular organ since it is so sized. As to claim 12, portion 12c of Taylor is considered to be the claimed longitudinal structure while the main portion of tube 12 is considered to be the claimed "tube". As to claim 13, distal portion 12c of the longitudinal structure 12 is tapered. As to claims 18-27, Taylor discloses balloons 22, 24.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (3,952,742). Taylor fails to disclose the distal portion of the longitudinal structure 12 as being externally threaded. However, it was well known to provide external threads on surgical devices so that they can more effectively penetrate

Art Unit: 3731

tissue and be secured thereto. It would have been obvious to include external threads on the Taylor structure 12 so that it too would have this advantage.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
October 7, 2003



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731